UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

MARLON BOWLES	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 1:20-cv-07413
	)	
ABBVIE INC., ABBVIE 1-100 AND ABBOTT 1-100	)	
	)	
Defendants.	)	

DEFENDANT ABBVIE INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)

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I. INTRODUCTION

Texas law, which applies in this products liability case,[1] bars this action in its entirety. Plaintiff claims that he was injured as a result of his use of HUMIRA®, a medication that is FDA-approved for the treatment of plaintiff's psoriatic arthritis. Section § 82.007 of the Texas Civil Practice and Remedies Code imposes a presumption that manufacturers of FDA-approved pharmaceutical drugs are not liable for warnings-based claims. While that presumption may be rebutted under certain limited exceptions, Plaintiff has failed to plead facts to establish any of those exceptions.

Moreover, even if Section 82.007 does not bar all of Plaintiff's claims, some of his claims still fail for independent reasons. AbbVie Inc. ("AbbVie") respectfully requests that the Court dismiss, with prejudice, Plaintiff's Complaint in its entirety.

II. BACKGROUND

This products liability case alleges defects in the warnings of HUMIRA, a prescription drug manufactured by AbbVie. As the Complaint acknowledges, the FDA first approved HUMIRA for use (for rheumatoid arthritis only) on December 31, 2002. *See* Compl., at ¶ 19.[2]

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[1] Plaintiff is a resident of Texas. Compl. [ECF No. 1] at ¶ 7. Upon information and belief, Plaintiff was prescribed HUMIRA in Texas, injected HUMIRA in Texas, and was allegedly injured in Texas. Therefore, Texas substantive law will apply in this diversity case. *Paulsen v. Abbott Labs.*, No. 15-CV-4144, 2018 WL 1508532, at *12-13 (N.D. Ill. Mar. 27, 2018); *Townsend v. Sears Roebuck & Co.*, 879 N.E.2d 893, 901 (Ill. 2007); *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 865–66 (7th Cir. 2010); *Gray v. Abbott Laboratories, Inc.*, 2011 WL 3022274, at *3 (N.D. Ill. July 22, 2011).

As an aside, Plaintiff's counsel is also from Texas, but it does not appear, at least from the face of the Complaint, that Plaintiff has conformed with Local Rule 83.15(a), which requires nonresident attorneys to designate local counsel, with an office in the Northern District, upon whom papers may be served.

[2] *See also* U.S. Food and Drug Administration Website, Approval Letter for HUMIRA (Dec. 31, 2002) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/adalabb123102L.htm (last visited Jan. 26, 2021). This FDA approval letter is a matter of public record, is publicly available, and is subject to judicial notice. AbbVie's use of the HUMIRA FDA Approval letter and other agency determinations does not convert this Motion into one for summary judgment. *See Vincent v. Medtronic, Inc.*, 221 F. Supp. 3d 1005, 1009 (N.D. Ill. 2016) (Considering, at the 12(b)(6) stage, an FDA approval letter and

In October 2005, the FDA approved psoriatic arthritis as an additional indication for HUMIRA,[3] for which Plaintiff was prescribed HUMIRA.

Between March and April 2018, Plaintiff "received a total of three doses of HUMIRA" to treat his psoriatic arthritis. Compl. at ¶¶ 57-58. On April 27, 2018, Plaintiff was admitted to the hospital where he was diagnosed with (and treated for) "acute renal failure secondary [to] minimal change disease, nephrotic syndrome secondary to minimal change disease, acute glomerulonephritis, . . . and interstitial lung disease." *Id*. at ¶ 59-60. Plaintiff asserts that HUMIRA caused or contributed to the conditions for which he was hospitalized in April 2018 and subsequent health problems. He filed this lawsuit against AbbVie on December 15, 2020.

Plaintiff's central allegation in this action is that AbbVie failed to adequately warn of the risks of kidney failure and/or interstitial lung disease (ILD) and those alleged defects in HUMIRA's warnings proximately caused Plaintiff's injuries. Plaintiff asserts seven causes of action: (1) Strict Liability – Failure to Warn (¶¶ 63-65); (2) Negligence (¶¶ 66-102); (3) Breach of Implied Warranty (¶¶ 103-107); (4) Breach of Express Warranty (¶¶ 108-111); (5) Fraud (¶¶112-116); (6) Negligent Misrepresentation (¶¶117-123); and (7) Gross Negligence (¶¶124-137). AbbVie now moves to dismiss all seven of Plaintiff's claims on the basis that they are barred under Texas law.

III. RULE 12(b)(6) STANDARD

Federal Rule of Civil Procedure 12(b)(6) authorizes a court to dismiss a cause of action that fails "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To avoid

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stating that "as publicly-available government agency determinations that appear on an agency website, these approvals by the FDA are subject to judicial notice.").

[3] U.S. Food and Drug Administration, Supp. Approval Letter for HUMIRA (Oct. 3, 2005) *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/125057s0046ltr.pdf, attached as **Exhibit A**.

dismissal under Rule 12(b)(6), the complaint must contain "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citation omitted). "A claim has facial plausibility when the plaintiff pleads *factual content* that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (emphasis added). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* A conclusory assertion is a conclusion without "factual enhancement" to support the conclusion. *Id.* In other words, the complaint must offer more than an "unadorned, the-defendant-unlawfully-harmed-me accusation" to defeat dismissal. *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted)).

Although the court must accept well-pleaded facts as true, conclusory allegations are not entitled to a presumption of truth. *Id.* at 678-79. Additionally, when a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility." *Id.* (citation and quotations omitted). Finally, although Rule 8(a) requires only a "short and plain statement", that statement "must 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Fields v. Cty. of Cook*, No. 19-CV-02680, 2020 WL 5296926, at *3 (N.D. Ill. Sept. 4, 2020) (quoting *Twombly*, 550 U.S. at 555); *Brooks v. Ross*, 578 F.3d 574, 581-82 (7th Cir. 2009) (allegations must be specific enough to provide notice of the contours of a viable claim).

IV. ANALYSIS

A. All of Plaintiff's Claims are Warnings-Based Product Liability Claims Under Texas Law.

Under Texas law, a "[p]roducts liability action' means any action against a manufacturer or seller for recovery of damages arising out of personal injury … allegedly caused by a

defective product whether the action is based in … strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." Tex. Civ. Prac. & Rem. Code § 82.001(2). In Texas, there are three types of product liability defects: (1) marketing defect, (2) design defect, and (3) manufacturing defect. *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 382 (Tex. 1995). Most relevant to the allegations here is a "marketing defect," which is premised on a defendant's failure to warn. *Romo v. Ford Motor Co.*, 798 F.Supp.2d 798, 807 (S.D. Tex. 2011) ("A 'marketing defect' occurs when a defendant knows or should have known of a potential risk of harm presented by the product but markets it without adequately warning of the danger or providing instructions for safe use.").

Despite labeling some of his causes of action otherwise, Plaintiff's ***entire*** theory of the case is based on a marketing defect (*i.e.*, the failure to warn of kidney failure and/or ILD). For purposes of this Motion, Plaintiff's Complaint is broken down into two parts: General Factual Allegations (¶¶ 14-62) and Causes of Action (¶¶ 63-137). The Causes of Action do not inject any new factual theories or allegations into the Complaint; they are premised solely on the Factual Allegations. And while the Factual Allegations are completely unfounded, they nevertheless advance only ***one*** theory of liability—that AbbVie knew HUMIRA could cause kidney failure and/or ILD and never warned of those complications:

> The TNF blocker class of drugs have been heralded by some as a "miracle" treatment for rheumatoid arthritis. Undoubtedly, they do help many people. ***However, in the treatment of any disease with powerful medications, it is always very important for both the prescribing physician and the patient to be able to balance the potential benefits of a medication against the known risks***. (¶ 18) (emphasis added).
>
> Despite the ever-increasing evidence of HUMIRA causing or contributing to serious kidney injuries [as alleged in Paragraph 21], ***even today the package insert for HUMIRA does not contain any reference to kidney injuries***. (¶ 22) (emphasis added).

> ***At no time did Defendant seek to add warnings for kidney injuries to the package insert*** via Changes Being Effected as allowed under 21 C.F.R. § 314.70(c)(6)(iii)(A). (¶ 23) (emphasis added).
>
> ***At no time did Defendant request via a prior approval supplement that the FDA allow Defendant to add a warning for kidney injuries***, despite ever-increasing evidence concerning the relationship between HUMIRA and kidney injuries (¶ 24) (emphasis added).
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> ***Had Petitioner been adequately warned of the increased risk of injuries and life-threatening side effects***, he would have chosen to request other prescription medications and avoided HUMIRA's injuries and potentially life-threatening side effects. (¶ 34) (emphasis added).
>
> ***Defendant negligently, recklessly and wantonly failed to warn Petitioner, Petitioner's physicians, and the general public, of the risks associated with taking HUMIRA***. Defendant failed to do so even after various studies, including their own, showed that there were problems concerning the risk of serious kidney injuries associated with HUMIRA. (¶ 41) (emphasis added).
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> ***As set forth more fully in the counts for Negligence and Strict Liability-Failure to Warn, these regulations [,which are cited discussed in Paragraphs 44-49,] all relate to monitoring the safety of HUMIRA and labeling changes required to properly inform Petitioner and Petitioner's health care professionals***. Because Defendant failed to properly monitor the safety of HUMIRA as required under 21 C.F.R. § 600.80 the label for HUMIRA was never properly updated as required by 21 C.F.R. § 201.57. (¶ 50) (emphasis added).
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> ***The purpose of the safety surveillance regulations, 21 C.F.R. § 600.80, and the labeling regulations 21 C.F.R. § 201.57 are to ensure that Petitioner and Petitioner's health care professionals were provided relevant safety information*** concerning HUMIRA. Any failure to comply with these regulations directly affected Petitioner. (¶ 52) (emphasis added).

This is Plaintiff's theory of the case. And while he rattles off a few legal terms of art in the Causes of Action section such as "design, failure to adequately test, and manufacture," Plaintiff never alleges a single fact to support those buzzwords. *See infra* pt. IV.C.1; *see also*

Phares v. Actavis-Elizabeth LLC, 892 F.Supp.2d 835, 839 (S.D. Tex. Aug. 30, 2012) ("Texas law considers most of the foregoing claims [including negligence, strict liability, and fraud] as failure to warn [products liability] claims.") (also citing to Tex. Civ. Prac. & Rem. Code § 82.001(2)). Simply put, this is a warnings case, and under Texas law, a warnings case against an FDA-approved pharmaceutical product, like HUMIRA, is barred.

B. All of Plaintiff's Claims Fail Under Section 82.007.

Texas law creates a rebuttable presumption that a manufacturer of an FDA-approved drug is not liable for "warnings or information":

> (a) In a ***products liability action alleging that an injury was caused by a failure to provide adequate warnings or information*** with regard to a pharmaceutical product, there is a ***rebuttable presumption that the defendant . . . [is] not liable*** with respect to the allegations involving failure to provide adequate warnings or information if:
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> (1) the warnings or information that accompanied the product in its distribution were those ***approved by the United States Food and Drug Administration*** . . . .

Tex. Civ. Prac. & Rem. Code Ann. § 82.007 (a)(1) (emphasis added). Plaintiff may only rebut this presumption in the following five scenarios: (1) AbbVie committed fraud on the FDA; (2) AbbVie sold HUMIRA after the FDA ordered it removed from the market; (3) AbbVie promoted HUMIRA for an unapproved use and that use caused the injury; (4) AbbVie prescribed HUMIRA for an unapproved use and that use caused the injury; or (5) AbbVie bribed an FDA official, causing the FDA-approved warnings to be inadequate. *Id*. at § 82.007 (b)(1 – 5); *Gonzalez v. Bayer Healthcare Pharms.,*930 F.Supp.2d 808, 820 (S.D. Tex. 2013). Even assuming every allegation in Plaintiff's Complaint is true, Section 82.007 bars all of Plaintiff's claims as a matter of law.

1. HUMIRA's Warnings Were Approved by the FDA, so AbbVie is Entitled to the Rebuttable Presumption in Section 82.007 (a)(1).

AbbVie is entitled to the rebuttable presumption laid out in subsection (a)(1) because the FDA approved HUMIRA's warnings that are at issue in this case. Indeed, Plaintiff admits in his Complaint that the FDA approved HUMIRA on December 31, 2002 (Compl. at ¶ 19), that HUMIRA was subject to continuing post-approval FDA oversight and regulations (*id*. at ¶¶ 44-52) and that Plaintiff used HUMIRA for its "intended purpose[] . . ., to treat psoriatic arthritis." *Id*. at ¶ 88. More importantly, as part of the approval and post-approval process, the FDA not only approved HUMIRA's original label in December 2002 but also approved over fifty supplements to the HUMIRA label (the last being on 12/16/2020).[4]

Here, Plaintiff allegedly took HUMIRA between March – April 2018. Compl. at ¶ 57. The HUMIRA label in effect at that time was approved by the FDA on December 14, 2017.[5] AbbVie is entitled to the presumption that it is not liable for "failure to provide adequate warnings or information . . . ." § 82.007 (a).

2. Plaintiff Has Not Alleged—And Indeed Cannot—Any Legally Valid Exception to AbbVie's Presumption of Non-Liability.

Plaintiff cannot rebut AbbVie's presumption of non-liability because the only possible statutory exception[6] Plaintiff could attempt to cling to is (b)(1)—that AbbVie withheld or

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[4] U.S. Food and Drug Administration Website, Approval Date(s) and History, Letters, Labels, Reviews for BLA 125057, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125057 (last visited Jan. 26, 2021).

[5] U.S. Food and Drug Administration, Supp. Approval Letter for HUMIRA (Dec. 14, 2017) *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/125057Orig1s403ltr.pdf, attached as **Exhibit B**. Moreover, a copy of the December 2017 FDA-Approved HUMIRA label, which is attached as **Exhibit C**, can be accessed here: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125057s403lbl.pdf

[6] The other exceptions in Texas Civil Practice and Remedies Code § 82.007(b) (b)(2 – 5) are inapplicable because Plaintiff has not plead any facts to support them:

misrepresented information to the FDA regarding HUMIRA (*i.e.*, that AbbVie committed "fraud on the FDA"). Indeed, subsection (b)(1) is preempted by the Federal Food, Drug, and Cosmetic Act (FDCA) unless there has been an actual FDA finding of fraud. *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 380 (5th Cir. 2012).

In *Lofton*, the Fifth Circuit affirmed the dismissal of a failure-to-warn claim despite the plaintiff's invocation of subsection (b)(1), finding that this statutory exception is the type of fraud-on-the-FDA provision preempted by the FDCA. *See id.* The crux of subsection (b)(1) lies in the FDCA disclosure mandates, which requires evidence that the manufacturer withheld from the FDA "required information that was material and relevant." *Id*. at 379. The Fifth Circuit reasoned that "[t]he term 'required information' refers to federal requirements under the FDCA; what is 'material' and 'relevant' must be determined by FDA itself, not by state court juries." *Id.* Therefore, subsection (b)(1) exists "solely by virtue of the FDCA disclosure requirements[,]" which, according to the Supreme Court, warrants preemption. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

In concluding its analysis, the Fifth Circuit considered the policy concerns underlying the Supreme Court's *Buckman* decision and determined that those policies would be furthered by preempting subsection (b)(1). *Lofton*, 672 F.3d at 380. Specifically, the concern is that if state-

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§ 82.007(b)(2):	There is no allegation that AbbVie sold HUMIRA after the FDA ordered HUMIRA off the market (HUMIRA is still on the market).
§ 82.007(b)(3):	Plaintiff admits that he took HUMIRA for an approved indication (psoriatic arthritis).
§ 82.007(b)(4):	There is no allegation that AbbVie prescribed HUMIRA (because a drug like HUMIRA may only be prescribed by a licensed physician), and Plaintiff admits that he took HUMIRA for an approved indication (psoriatic arthritis).
§ 82.007(b)(5)	There is no allegation that AbbVie bribed a public official under 18 U.S.C. § 201 to keep references to kidney failure and/or ILD out of HUMIRA's labels.

law claims proceed despite contrary law or regulation then (1) manufacturers would flood the FDA with information to ensure they retain the state-law presumption of non-liability, which takes away the FDA's control to "intelligently limit" disclosures and (2) the FDA's processes would be invaded when close questions of "withholding" information or "misrepresentations" arose. *Id.* Therefore, the Fifth Circuit held that Section 82.007(b)(1) "is preempted unless the FDA itself has found fraud." *Id.*

AbbVie anticipates that Plaintiff will attempt to side-step the preemption of (b)(1) by asking the Court to connect-the-dots between a Michigan statutory affirmative defense, a Second Circuit Court of Appeals decision from 2006, and the Texas statute at issue in this case. To the extent Plaintiff makes these arguments they should be rejected—which is what the other Federal Circuit Court of Appeals have done that have considered the issue.

Specifically, Michigan law provides an absolute defense to ***all*** product liability claims (as opposed to just warnings, like in Texas) for manufacturers of FDA-approved drugs. *See* Mich. Comp. Laws. § 600.2946 (5). In 2006, the Second Circuit in *Desiano* was tasked with deciding whether subsection (a) of Michigan's statute was preempted under *Buckman*. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d. Cir. 2006). The Second Circuit determined that it was not—holding that the plaintiff was permitted to bring products liability claims against the defendant because (1) there is a federal presumption against preemption, (2) the plaintiff's claims were traditional products liability claims, which do not require evidence of "fraud on the FDA," and (3) the Michigan statute creates an affirmative defense, which means "fraud on the FDA" is not a required element of Plaintiff's claims. *Id*. at 93-96.

The Second Circuit's *Desiano* decision has been rejected by two federal circuits since it was decided. First, the Sixth Circuit held that subsection (a) of the Michigan statute was

preempted under *Buckman* and thus affirmed the dismissal of the plaintiff's claims. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551-54 (6th Cir. 2012)[7]. Second, and as discussed above, the Fifth Circuit in *Lofton*—which is the ***only*** federal circuit court to address the Texas statute—held that § 82.007(b)(1) was preempted under *Buckman*. 672 F.3d at 380. In reaching this decision, the Fifth Circuit closely scrutinized and rejected *Desiano's* analysis—stating that "[i]n cases like this, where the FDA has not found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities." *Id*. This Court should follow the only federal circuit court to address the issue and find that subsection (b)(1) is preempted. *See also Atkinson v. Luitpold, Pharms., Inc.*, 448 F.Supp.3d 441 ("Although this Court is not bound by the Fifth Circuit's rulings, it bears consideration that the Fifth Circuit, which is conversant with Texas law, found that the presumption against preemption did not apply in a Section 82.007(b)(1) case."). Because the FDA has never found fraud against AbbVie regarding HUMIRA, and Plaintiff does not allege otherwise, Section 82.007(b)(1) does not apply.

Therefore, Plaintiff cannot, as a matter of law, rebut AbbVie's presumption of non-liability and AbbVie is entitled to a dismissal of this entire action with prejudice. *See id.* at 452 (granting the defendant's Rule 12(b)(6) motion and holding that because the "rebuttable presumption in Section 82.007(a)(1) applies here, and because Plaintiff's only argument to rebut the presumption is preempted, [the plaintiff's five claims based on failure to warn] shall be dismissed with prejudice."); *Parchim v. Biogen Inc.*, No. 619CV00524ADAJCM, 2019 WL 9654875, at *2 (W.D. Tex. Dec. 5, 2019) ("Under Texas law, if the claim is based on the

[7] The Sixth Circuit in *Marsh* refused to consider the Second Circuit's analysis from *Desiano*—stating in a footnote that it would follow the Sixth Circuit's prior decisions on the issue. *Id*. at n. 6.

product's labeling, its omissions, or inaccuracies, it falls under the purview of Section 82.007 regardless of how it is pleaded.")

C. To the Extent Any of Plaintiff's Claims Are Not Premised on Failure-To-Warn, Dismissal is Still Required.

While AbbVie maintains that all Plaintiff's claims are premised on assertions regarding HUMIRA's labeling, its omissions, or inaccuracies, Plaintiff's severely truncated legal descriptions allege various conduct by AbbVie in passing. Out of an abundance of caution, AbbVie addresses those allegations below.[8]

1. Negligence/Gross Negligence.

Plaintiff's cause of action titled "Negligence" (Compl. at ¶¶ 66-102) is nearly incomprehensible. In part, it reads as follows:

> At all times herein, Defendant negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed marketed, labelled, packaged, prepared for use and sold HUMIRA and failed to adequately test and warn of the risks and dangers of HUMIRA. . . . .
>
> Defendant breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, marketing, advertisement, packaging, sale, testing, quality assurance, quality control, sale, and distribution of HUMIRA in interstate commerce, in that Defendant knew and had reason to know that a consumer's use and injection of HUMIRA created a significant risk of suffering unreasonably dangerous health related side effects, including Petitioner's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

[8] AbbVie submits that Plaintiff's claims for Strict Liability—Failure to Warn; Breach of Implied Warranty; Breach of Express Warranty; Fraud; and Negligent Misrepresentation are based solely on HUMIRA's "warnings and information." § 82.007(a). To the extent those claims are based on some other theory of liability, AbbVie lacks "fair notice" of those theories because they are not discernable from the face of the Complaint. *Fields*, 2020 WL 5296926, at *3 (quoting *Twombly*, 550 U.S. at 555).

Id. at ¶¶ 69; 77. Without copying and pasting every single paragraph, AbbVie submits that Plaintiff's Negligence claim, in its entirety, fails to plausibly allege ***any*** factual content that puts AbbVie on "fair notice" of the basis of this claim (other than failure to warn). *Fields*, 2020 WL 5296926, at *3 (quoting *Twombly*, 550 U.S. at 555). For instance, there are several passing references to buzzwords such as "testing", "design", and "manufacture" (*see* ¶¶ 68, 69, 77, 78, 79, 81, 86, 91), but there are not any factual allegations describing how AbbVie was negligent in testing, designing, or manufacturing HUMIRA. Each assertion is simply a one-word allegation in a laundry list of alternative theories. This lack of factual enhancement renders any such arguable claim nonactionable. *See Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 977 (S.D. Tex. 2012) (dismissing negligence claim based on failure to test HUMIRA where plaintiff did "not plead any facts to support [negligence claims]" beyond failure to warn).

Further, if the Court dismisses Plaintiff's "Negligence" claim, it also must dismiss Plaintiff's "Gross Negligence" claim. *Id*. at ¶¶ 124-127. Under Texas law, a gross negligence claim cannot stand independently without a negligence claim. *See Schouest v. Medtronic, Inc.*, 92 F. Supp. 3d 606, 613 (S.D. Tex. 2015) ("Because the court has dismissed all negligence claims upon which gross negligence could be predicated, it must also dismiss [plaintiff]'s gross negligence claim."); *Trevino v. Lightning Laydown, Inc.*, 782 S.W.2d 946, 949 (Tex. App. 1990), *writ denied* (May 9, 1990) ("[O]ne's conduct cannot be grossly negligent without being negligent.")

Therefore, to the extent Plaintiff's Negligence and Gross Negligence claims purportedly includes any claims other than those premised on failure to warn, such claims require dismissal for failure to satisfy the requisite pleading standard.

2. Breach of Warranty Claims

In addition to failing under Section 82.007, Plaintiff's two warranty claims (Breach of Implied Warranty and Breach of Express Warranty) must be dismissed because Plaintiff has not alleged that he provided pre-suit notice of the alleged breach, which is required under Texas law. *See Morgan v. Medtronic, Inc.*, 172 F. Supp. 3d 959, 970 (S.D. Tex. 2016) ("To bring a breach of warranty claim, a plaintiff 'must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from remedy.'") (quoting Tex. Bus. & Com. Code § 2.607(c)(1)).

Moreover, Plaintiff's express warranty claim does not identify any specific affirmation of fact or promise that AbbVie breached—other than a conclusory allegation that AbbVie warranted "that HUMIRA is safe, effective, fit and proper for its intended use." Compl. at ¶ 109. Under Texas express warranty law, Plaintiff is required to prove "that [AbbVie] made a ***specific*** promise or affirmed a ***specific*** fact." *City of Port Arthur v. Daimler Buses N. Carolina, Inc.*, No. 1:15-CV-00186-MAC, 2018 WL 3596863, at *3 (E.D. Tex. July 12, 2018) (emphasis in original). Plaintiff's Complaint does not set forth any alleged facts regarding the specifics of the contents of AbbVie's alleged warranty, nor is it clear whether the alleged warranties were made to Plaintiff himself or his prescribing physician. *See Gonzalez v. Bayer Healthcare Pharm., Inc.*, 930 F. Supp. 2d 808, 818 (S.D. Tex. 2013) ("Plaintiff's breach of warranty claims are also subject to the learned intermediary doctrine claims. She fails to state a plausible claim because she does not allege what warranties were made to her prescribing physician nor state how they were breached, leaving only 'an unadorned, the defendant-unlawfully-harmed-me accusation.'"); *Steen v. Medtronic, Inc.*, No. 310-CV-936-L, 2010 WL 2573455, at *3 (N.D. Tex. June 25, 2010) (dismissing complaint where plaintiff did not "allege any facts showing when and how he

received notice of such warranties" or "fact showing the pacemaker did not comport with such warranties").

Moreover, AbbVie never made any promises to physicians or patients about any specific outcomes, such as guaranteed benefits or a lack of side effects. To the contrary, the labeling—which was and remains FDA approved—warned of the risks and benefits associated with HUMIRA so that the prescribing physician could make the decision about whether the medication was appropriate for a particular patient.

V. CONCLUSION

All seven of Plaintiff's claims fail as a matter of law either entirely under the presumption of Section 82.007, or individually as stand-alone claims. AbbVie respectfully requests that the Court dismiss Plaintiff's Complaint in its entirety with prejudice because any possible amendment would be futile under Texas law. *Vargas-Harrison v. Racine Unified Sch. Dist.*, 272 F.3d 964, 974 (7th Cir. 2001) ("[W]e nevertheless must affirm the dismissal because an examination of the proposed amended complaint . . . make[s] clear that the amendment would have been futile.")

Dated: February 2, 2021

Respectfully submitted,

/s/Patricia Brown Holmes

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CERTIFICATE OF SERVICE

I hereby certify that on February 2, 2021, the foregoing document was filed using the Court's CM/ECF system, which will send notification of this filing to all attorneys of record who have registered for CM/ECF updates.

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